COUNTY OF LOS ANGELES
Public Health

CYNTHIA A. HARDING, M.P.H.
Interim Director

JEFFREY D. GUNZENHAUSER, M.D., M.P.H.
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October 21, 2014

ADOPTED
BOARD OF SUPERVISORS
COUNTY OF LOS ANGELES
23 of October 21, 2014

Sachi A. Hamai
SACHI A. HAMAI
EXECUTIVE OFFICER

The Honorable Board of Supervisors
County of Los Angeles
383 Kenneth Hahn Hall of Administration
500 West Temple Street
Los Angeles, California 90012

Dear Supervisors:

AUTHORIZATION TO ACCEPT AND IMPLEMENT AN AWARD AND FUTURE AWARDS AND/OR AMENDMENTS FROM THE COUNCIL OF STATE AND TERRITORIAL EPIDEMIOLOGISTS FOR THE INFLUENZA INCIDENCE SURVEILLANCE PROJECT FOR THE PERIOD OF JULY 1, 2014 THROUGH JUNE 30, 2019 (All SUPERVISORAL DISTRICTS) (3 VOTES)

SUBJECT

Provide authorization to accept and implement an award and future awards and/or amendments from the Council of State and Territorial Epidemiologists to participate in the Influenza Incidence Surveillance Project for the period of July 1, 2014 through June 30, 2019.

IT IS RECOMMENDED THAT THE BOARD:

1. Authorize the Interim Director of the Department of Public Health (DPH), or her designee, to accept and implement an award (Exhibit I), from the Council of State and Territorial Epidemiologists (CSTE) to participate in the Influenza Incidence Surveillance Project (IISP), in the amount of $127,000, for the period of July 1, 2014 through June 30, 2015, subject to review and approval by County Counsel, and notification to your Board and the Chief Executive Office (CEO).

2. Delegate authority to the Interim Director of DPH, or her designee, to accept future awards and/or amendments that are consistent with the requirements of the CSTE award that extend the term through June 30, 2019 at amounts to be determined by the CSTE; reflect non-material and/or ministerial revisions to the award's terms and conditions; allow for the rollover of unspent funds and/or redirection of funds; adjust the term of the award through December 31, 2019; and/or provide an increase or decrease in funding up to 25 percent above or below each award term's annual base amount, subject to review and approval by County Counsel, and notification to your Board and the CEO.

PURPOSE/JUSTIFICATION OF RECOMMENDED ACTION

Approval of Recommendation 1 will allow DPH to accept funding to continue to participate in IISP. This project supports the ability of DPH's Acute Communicable Disease Control Program and Public Health Laboratory to determine and report in real time, the locality-specific weekly incidence of influenza like illness and laboratory confirmed influenza among persons seeking medical care for acute respiratory infections.

Tracking the incidence of influenza allows for disease burden comparisons, alerts public health officials of increases beyond usual seasonal activity, and improves tracking measures. IISP reports the incidence of influenza like illness and laboratory confirmed influenza throughout the flu season which begins in August of each year. The IISP tests protocols that can meet the needs for increased surveillance during a pandemic, such as timely test result confirmation.

In addition, the IISP award provides funding for a part-time Public Health Microbiologist and part-time Epidemiology Analyst to determine and report in real time the incidence of influenza like illness and laboratory confirmed influenza for one year. This is in support of the Pandemic and All-Hazard Preparedness Act to enhance public health security preparedness by tracking, analyzing, and sharing data to enhance early detection and rapid response to public health emergencies.

Approval of Recommendation 2 will allow DPH to accept future awards and/or amendments that are consistent with the requirements of the forthcoming award to extend and/or adjust the term of the award; reflect non-material revisions to terms and conditions; rollover unspent funds and/or redirect funds; and/or provide an increase or decrease in funding up to 25 percent above or below each grant term's annual base amount. This recommended action will enable DPH to accept awards and/or amendments that adjust the project period up to six months beyond the original term, in those instances where there has been an unanticipated extension of the term to allow additional time to complete services and utilize grant funding. This authority is being requested to enhance DPH's efforts to expeditiously maximize grant revenue, consistent with Board policy 4.070: Full Utilization of Grant Funds.

Implementation of Strategic Plan Goals

The recommended actions support Goal 3, Integrated Services Delivery, of the County's Strategic Plan.

FISCAL IMPACT/FINANCING

DPH will accept an award from the CSTE to continue to participate in the IISP, in the amount of $127,000, for the period of July 1, 2014 through June 30, 2015 as well as funding for four subsequent terms, through June 30, 2019, at amounts to be determined by the CSTE.

IISP funds will support DPH personnel and operating costs to continue to determine and report in real time, the locality-specific weekly incidence of influenza like illness and laboratory confirmed influenza among persons seeking medical care for acute respiratory infections.

Funding is included in DPH's fiscal year 2014-15 Final Adopted Budget and will be included in future

fiscal years, as necessary.

FACTS AND PROVISIONS/LEGAL REQUIREMENTS

The IISP was initiated during the 2009 H1N1 influenza pandemic to monitor the age-specific incidence of medically-attended influenza like illness and influenza-associated influenza like illness in real time throughout the influenza season. In June 2010, DPH received funding as one of twelve states and/or local health agencies to participate in the IISP project. Since then, DPH has participated in the IISP project.

On September 7, 2010, your Board authorized DPH to accept an award from the CSTE in the amount of $220,606, for the period of June 1, 2010 through May 31, 2011. In addition, your Board delegated authority to DPH to accept future IISP awards from the CSTE through May 31, 2016, with substantially similar terms to the current award, that do not exceed the prior year's base award by more than 25 percent, subject to review and approval by County Counsel and the CEO, and notification to your Board.

Under this delegated authority, DPH notified your Board on May 26, 2011; August 20, 2012 and May 1, 2013; and October 30, 2013, respectively, of the acceptance of $190,000 for the period of June 1, 2011 through May 31, 2012; $190,000 for the period of June 1, 2012 through August 31, 2013; and $85,000 for the period of July 1, 2013 through June 30, 2014.

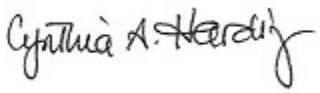
In May 2014, DPH submitted an application in response to an IISP Funding Opportunity Announcement. On September 11, 2014, DPH received the notice of award from the CSTE, in the amount of $127,000 for the period of July 1, 2014 through June 30, 2015, to continue DPH's participation in the IISP. The 2014-15 award exceeds the authority delegated to DPH to accept awards that do not exceed the prior year's base award by more than 25 percent.

County Counsel has reviewed and approved Exhibit I as to form. The award includes an indemnification provision which requires the County to indemnify the CSTE for all liability arising from the acts and omissions of the County in its performance under the award. This is a standard requirement from the CSTE and cannot be waived or modified.

IMPACT ON CURRENT SERVICES (OR PROJECTS)

Approval of the recommend actions will allow DPH to continue to participate in the IISP to determine and report in real time, the locality-specific weekly incidence of influenza like illness and laboratory confirmed influenza among persons seeking medical care for acute respiratory infections.

Respectfully submitted,



Cynthia A. Harding, M.P.H.
Interim Director

CAH:nms

Enclosures

c: Chief Executive Officer
County Counsel
Executive Officer, Board of Supervisors

GENERAL CONTRACT AGREEMENT

BUYER: **Council of State & Territorial Epidemiologists (CSTE)** 2872 Woodcock Blvd., Suite 250 Atlanta, GA 30341-4015 Phone: (770) 458-3811 Fax: (770) 458-8516	**SELLER:** Los Angeles County Department of Public Health 313 North Figueroa Street Los Angeles, CA 90012 Phone: (213) 240-7941
CSTE AUTHORIZING OFFICIAL: Jeffrey Engel, MD Executive Director	**AUTHORIZING OFFICIAL:** Cynthia A. Harding, MPH Chief Deputy Director
CSTE PROJECT MANAGER: Nicole Bryan Associate Research Analyst Phone: (770) 458-3811 Email: nbryan@cste.org	**PROJECT MANAGER:** Laurene Mascola, MD, MPH, FAAP Chief, Acute Communicable Disease Control Program Los Angeles County Department of Public Health Phone: (213) 240-7941 Email: lmascola@ph.lacounty.gov

PROJECT/PRODUCT DESCRIPTION (See Article I and Statement of Work, Attachment 1):
Development and full participation in Influenza Incidence Surveillance Pilot Project

DELIVERY SCHEDULE: See Statement of Work for delivery schedule (Article I and Attachment 1)

PERIOD OF PERFORMANCE:	Start Date: July 1, 2014	End Date: June 30, 2015

CONTRACT PRICE (See Article II): not to exceed **$127,000.00**

PAYMENTS TERMS (See Article IV)::
Funds shall not exceed the contract price above and will be dispersed upon receipt of invoices from the seller for allowable costs and fees actually incurred and chargeable to CSTE in accordance with the budget categories indicated in Attachment II.

The award will be made according to the schedule below:
October 1, 2014 – 25%
January 1, 2015 – 25%
April 1, 2015 – 25%
June 30, 2015 – 25%

A final invoice and report is due by **June 30, 2015**.

TYPE OF CONTRACT: Fixed Price Contract (See Article III)

TERMS AND CONDITIONS: See Articles I through XXIV included as a part of this agreement for applicable Terms and Conditions.

_____ **Jeffrey Engel, MD** **Executive Director** **Council of State & Territorial Epidemiologists**	_____ **Cynthia A. Harding, MPH** **Chief Deputy Director** **Los Angeles County Department of Public Health**

GENERAL CONTRACT AGREEMENT

CONTRACT TERMS AND CONDITIONS

Article I – Statement of Work

More details are set forth in Seller's Statement of Work as appended hereto as Attachment 1.

Article II – Cost

A. The total price to CSTE for the performance of this General Contract Agreement shall not exceed **$127,000.00** unless changed by written amendment to this Agreement. All funding shall be contingent upon the availability of funds from the CDC **(Cooperative Agreement No. 1U38 OT000143)**.
B. Seller's budget is appended hereto as Attachment II.

Article III – Type of Contract

This Agreement is considered a Fixed Price contract. It is recognized by both parties that the actual price for this project may vary either above or below the price set forth in Article II, but will have no effect on that price, unless amended as set forth in Article XVI.

Article IV - Payment

A. CSTE shall reimburse Seller for allowable costs and fees actually incurred and chargeable to CSTE in accordance with the budget categories indicated in Attachment II upon being invoiced by Seller and upon approval of the invoice by CSTE's Executive Director. Invoices shall be submitted for partial payments or in full to:

    Nicole Bryan
    Council of State and Territorial Epidemiologists
    2872 Woodcock Boulevard
    Suite 250
    Atlanta, GA 30341-4015

B. Payment shall be made by CSTE within thirty (30) days of receipt of invoice. All checks should be made payable to:

    Los Angeles County Department of Public Health

    and mailed to:

    Financial Management
    Attn: Revenue Unit
    5555 Ferguson Drive, Room 100-50
    Commence, CA 90022

Article V – Publicity

No party will use the name of any other party in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party.

Article VI – Governing Laws

This Agreement shall be governed and construed in accordance with laws of the State of Georgia.

Article VII – Regulatory Compliance

A. The Seller agrees to comply with and abide by all relevant and applicable laws and regulations of federal, state, and local governments/agencies.
B. Seller assures that adequate safeguards shall be taken whenever using human subjects in research projects and an institutional review committee composed of sufficient members with varying backgrounds to assure complete and adequate review of projects involving the use of human subjects has reviewed and approved the projects. Seller will abide by all applicable

provisions of the U.S. Department of Health and Human Services regarding the use of human subjects.

Article VIII – Rights in Data, Publication, and Copyright

The Funding Agency reserves a royalty-free, nonexclusive, and irrevocable license to reproduce, publish or otherwise use, any work developed under the Agreement.

Article IX – Intellectual Property

Existing and/or already conceived inventions, discoveries, patents, products, or other information developed in whole or part in connection with this agreement shall be the exclusive property of CSTE in accordance with 37 CFR Part 401.

Article X – Termination

A. Either party may terminate this Agreement hereto by giving written notice to the other party seven (7) days in advance of a specified date of termination.
B. Upon receipt of such notice from CSTE, Seller shall take all necessary action to cancel outstanding purchase orders and other commitments relating to the project under this Agreement, and shall exercise reasonable diligence to cancel or redirect commitments for personnel services to its other activities and operations.
C. CSTE shall remain liable for all cost incurred under this Agreement, including any of the above mentioned commitments entered into by Seller in good faith prior to the receipt of the termination notice. Upon payment of such costs, CSTE shall be entitled to, and Seller agrees to deliver, the information and items, which, if the Agreement had been completed, would have been required to be furnished to CSTE.

Article XI – Non-Solicitation Agreement

During the term of this Agreement and for one (1) year thereafter, neither party nor any of their affiliates will offer work to, solicit or induce for employment, employ, or contract with, personnel of CSTE or their affiliates, without first obtaining the written consent of applicable Managing Directors.

Article XII – Independent Contractor

A. In the performance of all services hereunder, Seller shall be deemed to be and shall be an independent contractor.
B. No party is authorized or empowered to act as agent for any other for any purpose and shall not on behalf of any other enter into any contract, warranty, or representation as to any matter. None shall be bound by the acts or conduct of any other.

Article XIII – Indemnification

A. CSTE assumes all risk of liability with respect to its performance of any activities relating to this project, other than liability arising out of an act of omission of Seller, and shall indemnify and hold Seller harmless from all liability arising out of acts or omissions of CSTE, its employees and agents.
B. Seller assumes all risk of liability with respect to its performance of any activity relating to this project, other than liability arising out of any act or omission of CSTE, and shall indemnify and hold CSTE harmless from all liability arising out of acts or omission of Seller, its employees and agents.

Article XIV – Nondiscrimination and Affirmative Action

Seller certifies that it has an active program for compliance with all applicable state and federal regulations, executive orders and legislation concerning non-discrimination, equal opportunity, or affirmative action, and that, whenever required, valid assurances of compliance are on file with the cognizant enforcement agency. Whenever applicable, the above statement of certification includes, but is not necessarily limited to, the following acts:

- Title IV of the Civil Rights Act of 1964
- Executive order 11246, “Equal Employment Opportunity,” as amended by E.O. 11375, Amending Executive Order 11246 Relating to Equal Employment Opportunity,” and as

supplemented by regulations at 41 CFR Part 60, “Office of Federal Contract Compliance Programs, Equal Employment Opportunity, Department of Labor

- Title VII of the Civil Rights Act of 1964 as amended by the EEO Act of 1972
- Section 504 of the Rehabilitation Act of 1973
- The Age Discrimination Act of 1975, as amended
- Affirmative Action Obligations of Contractors and Subrecipients for Disabled Veterans and Veterans of the Vietnam Era, Sub-part A, Paragraph 60-250.4
- Title IX of the Higher Education Act of 1972

Article XV – Seller Certifications

A. Debarment and Suspension
Seller certifies to the best of its knowledge and belief that it is not presently debarred, suspended, or proposed for debarment or declared ineligible for the awards of Contracts, by any Federal Agency, in accordance with OMB Guidelines (53 FR19161-19211).

B. Certification of Non-Delinquency of Federal Debt
Seller certifies that it is in compliance with the Non-Delinquency on Federal Debt criteria, in accordance with OMB Circular A-129.

C. Certification of Drug-Free Workplace
Seller certifies that it has implemented appropriate policy in accordance with the Drug-Free Workplace Act of 1988, 45 CFR, Part 76, Subpart F.

D. Certification Regarding Lobbying
Seller certifies to the best of its knowledge and belief that no Federal appropriated funds have been paid or will be paid, by or on behalf of Seller, to any person or organization for influencing or attempting to influence an officer or employee of a Federal agency, a member of Congress, officer or employee of Congress, or an employee of a member of Congress in connection with obtaining any Federal contract, grant or any other award covered by 31 U.S.C. 1352.

E. Conflicts of Interest
Seller certifies that it has established Conflict of Interest Policy that complies with all requirements, rules and principles of 60 FR 35810, Part III incorporated herein by reference.

F. Misconduct in Science
Seller certifies that it has established as defined in Article XI, B, administrative policies as required by 42 CFR Part 50, Subpart A.

Article XVI – Changes

The Agreement may be modified or amended if the amendment is made in writing and signed by both parties.

Article XVII – Retention and Access to Records

Recipient shall retain records pertinent to this project for 3-years after the end of the project unless any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period. In the case of any of these actions, records shall be retained until all actions have been resolved. Recipient agrees to provide CSTE, the Comptroller General of the United States, and if appropriate, the State, through their duly authorized representative, access to and the right to examine all records, books, papers, or documents which are related to this project.

Article - XVIII – Clean Air Act and Federal Water Pollution Control Act

If the agreed to price of this agreement exceeds $100,000, Seller agrees to comply with all applicable standards, orders, or regulations issued pursuant to the Clean Air act, 42 U.S.C. 7401 et seq., and the Federal Water Pollution Control Act, as amended 33 U.S.C. 1251 et seq.

Article XIX – Debt Collection

HHS Claims Collection Regulations (45 CFR Part 30, Subpart B), provides for interest and penalties on all delinquent debts and will be applicable to this agreement if debt collection becomes necessary.

Article XX – Smoke-Free Workplace
Recipient agrees to provide a smoke-free workplace and promote the nonuse of tobacco products. Workplace is defined to mean office space (including private offices and other workspace), conference or meeting rooms, corridors, stairways, lobbies, rest rooms, cafeterias, and other public space.

Article XXI – Financial Audit
Recipient is subject to audit requirements as set forth in 45 CFR Part 74.26.

Article XXII – Confidentiality

Both parties acknowledge that during the course of this Agreement, each may obtain confidential information regarding the other party's business. Both parties agree to treat all such information and the terms of this Agreement as confidential and to take all reasonable precautions against disclosure of such information to unauthorized third parties during and after the term of this Contract.

Article XXIII – Severability

If any provision of this Contract shall be held to be invalid or unenforceable for any reason, the remaining provisions shall continue to be valid and enforceable. If a court finds that any provision of this Agreement is invalid or unenforceable, but that by limiting such provision it would become valid and enforceable, then such provision shall be deemed to be written, construed, and enforced as so limited.

Article XXIV - Warranty

Seller shall provide that any services provided under this contract will meet, or exceed, the local standard of similar service providers in the community. Further, any products provided under this contract shall meet the merchantability standards and meet fitness standards for the intended purpose.

Explained or stricken

IN WITNESS WHEREOF, the parties have caused these presents to be executed in duplicate.

_____	_____
Jeffrey Engel, MD	**Cynthia A. Harding, MPH**
Executive Director, CSTE	**Chief Deputy Director, Los Angeles County Department of Public Health**

Attachment I

Influenza Incidence Surveillance Project

1. Name: Los Angeles County Department of Public Health

2. Method of Selection: Competitive Bid

3. Period of Performance: July 1, 2014 – June 30, 2015

4. Scope of Work

Background

Influenza incidence varies with each seasonal epidemic and influenza A and B viruses cause differential disease by age, as evidenced by 2009 pandemic influenza A (H1N1) virus (pH1N1). Tracking the incidence of influenza allows for disease burden comparisons across predominant circulating virus types, seasonal epidemics, geographic regions, alerts public health officials of increases beyond usual seasonal activity, and improves measures of influenza that are currently non-specific, including influenza-like illness (ILI) and acute respiratory infections (ARI).
The Influenza Incidence Surveillance Project (IISP) was initiated in 2009 to monitor the age-specific incidence of medically-attended ILI and influenza-associated ILI in real time throughout the influenza season. Health care providers with a primary care focus and defined patient populations reported weekly the number of ILI cases and total number of patient visits. Specimens are collected from a subset of patients and tested using PCR for respiratory viruses including, influenza, RSV, adenovirus, rhinovirus, metapneumovirus, parainfluenza viruses and coronaviruses.
Each year of the project has included some variation in methods. During the 2009-10 surveillance period, only influenza was included in the test panel. In 2010-11, PCR testing for multiple respiratory pathogens and the inclusion of patients with respiratory illness that did not meet the ILI case definition were included. During 2011-12 and 2012-13, PCR testing for multiple respiratory viruses continued, but the tracking and collection of specimens from patients with non-ILI respiratory illness was optional. During the 2013-14 season, ILI specimen testing required only influenza, and optionally multi-pathogen testing. In addition, methodology varied between two available funding levels reflecting core and reduced activities. For the 2014-15 season, the IISP application will be open only to IISP sites for continuation of core methodology, with the option of adding or retaining multi-pathogen testing.

Objectives

1. Determine the prevalence and incidence of medically-attended ILI.

2. Determine the proportion of medically-attended ILI patients with laboratory-confirmed influenza.

3. Determine the incidence of laboratory-confirmed influenza among medically-attended ILI patients.

4. Describe the medically-attended ILI patient characteristics, both with and without influenza detection.

5. Describe the temporal trends of ILI and laboratory-confirmed influenza.

Methods

Seller will conduct surveillance consistently with current protocols:

Case Definitions

Influenza-like illness (ILI)

- <2 years of age: onset in the past 4 days of fever AND >1 of the following: rhinorrhea, nasal congestion, sore throat, cough
- ≥2 years of age: onset in the past 4 days of fever AND cough AND/OR sore throat

Note: patient report of fever is sufficient for the case definition requirements. ILI symptoms may have occurred anytime within the past 4 days; symptoms do not have to be present during the clinic visit.

Acute respiratory infections (ARI)

Onset in the past 4 days of > 2 of the following: rhinorrhea, nasal congestion, sore throat, cough, fever

Case Definition Table View

<table>
<tr><th>Symptoms within 4 days</th><th>ARI (all ages)</th><th>ILI (<2 years)</th><th>ILI (≥2 years)</th></tr>
<tr><td>Fever</td><td rowspan="5">Any two symptoms</td><td rowspan="5">✓

Any one symptom</td><td rowspan="5">✓

One or both of these two</td></tr>
<tr><td>Sore throat</td></tr>
<tr><td>Cough</td></tr>
<tr><td>Rhinorrhea</td></tr>
<tr><td>Nasal congestion</td></tr>
</table>

Recruitment of Health Care Providers

Provider type and size

Recipients are responsible for recruiting 5 to 6 health care providers willing to comply with the methods outlined in this guidance document. Providers must have the following characteristics and capabilities for inclusion in the surveillance project:

- Providers should be of a small to moderate size, such as those with a weekly patient volume of approximately 100-150 patients.
  Larger clinics may be considered, but must demonstrate the ability to maintain methodology across multiple staff members. The combination of all providers together for a site must represent all ages.
- Providers must be able to enumerate or estimate the patient panel by age group. This will serve as an approximation of a population for incidence calculation.
- Providers must be able to report by Tuesday of each week for data collected in the previous week, such that the health department may report results to CDC by 12pm Eastern time each Wednesday.

- Providers must be able to Collect appropriate specimens from patients and submit to the public health laboratory (PHL) within the recommended timeline.
- Providers must be able to submit specimens to the public health laboratory within the recommended timeline.

Patient population (aka "patient panel")

- There are two ways to enumerate the provider population:
  - Ideally, as the total number of patients registered with the provider.
  - However, an alternative is to count the average number of individual patients seen by the provider in a given year (3 years of data desired for making this estimation).
- Patient population should be enumerated by age group.
- **Please work closely with providers to determine the best method of determining the population they represent.** It may be worthwhile to assess the rates for each provider to determine if the data seem plausible given the age structure of the population served.

Surveillance Methods

1. Aggregate Data Reporting
   - Providers must report the following data weekly (Tuesday) as illustrated in the Influenza Incidence Surveillance Project Guidance (August 2014 – July 2015 Surveillance Period) **Appendix A**:
     - Number of all patient visits by age group
     - ILI visits by age group
     - ARI visits by age group (optional)
     - Age Groups are designated as follows:
       - <1 year
       - >1 - <2 years
       - >2 - <5
       - >5 - <18
       - >18 - <25
       - >25 - <50
       - >50 - <65
       - ≥65 years

2. Specimen and Additional Data Collection
   - Collect a respiratory specimen from the first ILI patients of the week **until they reach a count of 10**.
     - Persons meeting the case definition or definitions will be asked to undergo a nasal, nasopharyngeal (NP), oropharyngeal (OP), or dual NP/OP swab, unless one or more of these specimen types is not approved for influenza diagnostic testing and reporting.
     - Swabs must be collected by a trained medical officer, clinical officer, and nurse or laboratory technician.
     - Swabs must be immediately placed into 1-3mL viral transport media.

- Clinical staff will attempt specimen collection from each patient meeting the case definition until a total of 10 specimens have been collected during the week (Mon-Sat). Sites collecting specimens from ARI and ILI cases would collect up to 10 specimens from each group.

- Site coordinators, together with providers and laboratory personnel, may determine if specimens from patients meeting the ARI case definition should also be collected and tested using molecular testing methods.
- Specimen handling and submission:
  - All respiratory specimens must be kept at 4°C for **no longer than 72 hours** before testing and ideally should be tested within 24 hours of collection.
  - If storage longer than 72 hours is necessary, clinical specimens should be stored at -70°C. Freezing at higher temperatures (e.g. -20°C) can reduce the likelihood of virus detection.
  - Specimens should be transported such that they arrive at the health department within 72 hours of collection.
- Patients with a specimen collected must also have the demographic and clinical data form completed as illustrated in **Appendix B** of the Influenza Incidence Surveillance Project Guidance (August 2014 – July 2015 Surveillance Period).

3. Specimen Testing

- The participating state, city or county's Public Health Laboratory (PHL) will process and test specimens collected by providers.
- Influenza testing must be conducted in accordance with FDA guidelines using the CDC's influenza virus real-time RT-PCR diagnostic panel. Please refer to the Instructions for Use to determine all appropriate ancillary reagents.
- Laboratories must test for the following:
  - Non-specific Influenza A (subtypes 2009 H1N1, H1, H3)
  - Influenza B
- Influenza test results must be reported within 2 weeks of specimen collection.
- If conducting non-influenza respiratory virus testing, the test method for non-influenza respiratory virus testing is determined by the PHL, but must be a molecular platform (multiplexed PCR, real-time RT-PCR, microarray).
- Additional respiratory pathogens to consider testing routinely (reporting at the discretion of the PHL):
  - RSV
  - Adenovirus
  - Parainfluenza viruses 1-3
  - Human metapneumovirus
  - Rhinovirus
  - Coronaviruses
  - Parainfluenza 4
  - Enteroviruses
  - Bacterial pathogens

Deliverables and required activities

1) *Weekly* data reports must be submitted to CDC investigators by 12pm Eastern time each Wednesday.
    - ILI count data:
        - new file each week with only the previous week's data
        - contains ILI and total patient counts by age group **(FOA Appendix A)**
    - Patient data and summary test results:
        - a single cumulative file, updated each week
        - contains data collected by the provider in the demographic and clinical information form **(FOA Appendix B)**
        - contains results of PCR testing in summary form for each respiratory virus
            - Influenza results should be reported within 2 weeks of specimen collection
            - Other respiratory virus test result reporting may be determined by the PHL
2) *One- or few-time* data reports submitted to CDC investigators.
    - Participating health care provider classification and population data
        - one-time report at the time of provider enrollment
    - Detailed PCR test results:
        - format and reporting frequency will be determined by the PHL
          contains the laboratory test result values specific to the type of test performed (i.e., CT values for RT-PCR, MFI values for Luminex xTag RVP)

    All data reporting file formats are provided in the IISP Data Dictionary.

3) Agreement to retain residual specimen aliquots for possible shipment to CDC if determined necessary (will be determined by end of season).
4) Invoices must be sent on a quarterly schedule for receipt of funding on a Firm-Fixed type contract: **October 1 (25%), January 1 (25%), April 1 (25%), June 30 (25%).**
5) Reports describing progress towards meeting the stated objectives and completing the required deliverables must be submitted to CSTE quarterly. These reports may include data generated during the reporting period, progress associated with project, timeliness for completion of project, problems associated with the project, and projections and recommendations for the remainder of the project.
6) Provider compliance must be monitored weekly. Providers who fail to collect data and/or collect specimens on <60% of ILI patients are considered non-compliant. Non-compliant providers must be replaced if efforts to improve compliance have not been accepted within two weeks of identifying the provider as non-compliant.
7) Participate in in-person meetings as determined by CSTE and CDC (up to two), which may be a state site visit, state or CSTE/CDC hosted all participating sites meeting.

Travel

1) Seller agrees to fund and support at least one individual who is substantially involved in the project to a 2 day IISP analytic meeting (travel outside of the state will be required) or project meeting during the period between July 1, 2014 and June 30, 2015. This meeting is required and financial support for travel will be the responsibility of the agency (seller).
2) Seller agrees to fund and support at least one individual who is substantially involved in the project to attend the IISP analytic meeting at the 2015 CSTE Annual Conference June 14-18, 2015.

Roles and Responsibilities:

Recipient Rights and Responsibilities

Each recipient public health department and public health laboratory will have primary responsibility for the following:

- Providing scientific and management oversight for the overall project at participating sentinel provider sites, including surveillance design and conduct, data collection and reporting, quality control, and collaborations with other awardees, CDC, and CSTE.
- Appointing a coordinator to serve on the Planning and Coordination Committee, preferably the state/local influenza surveillance coordinator.
- Obtaining the appropriate human subjects clearances at local sites if required.
- Working with CDC scientists to refine protocols and data collection instruments.
- Performing laboratory tests and reporting data as specified in the surveillance protocols.
- Provide a mechanism of transporting specimens from sentinel provider sites to the state public health laboratory.
- Providing appropriate training for providers participating in the project.
- Providing written progress reports that describe performance milestones and invoices to CSTE as required in the contract agreement.
- Initiate a formal agreement with providers to ensure participation, submission of samples and data, to prohibit charging patients for the cost of rapid antigen tests.
- Agreement to participate in in-person meetings as determined by CSTE and CDC (up to two per year) and may be a state site visit, state hosted all participating sites meeting, or CSTE/CDC hosted meeting.
- Agreement to abide by the collaborative guidelines described in the Data Use Agreement.

CSTE Responsibilities

During the established grant period, CSTE is responsible for:

- Monitoring the terms of the contract agreement between the recipient and CSTE.
- Collecting invoices from the recipient and paying invoices according to the terms of the contract agreement between the recipient and CSTE.
- Providing information about the progress of the program to the CSTE Executive Board and to CDC.
- Reviewing and distributing progress reports and the final report with CDC.
- Providing technical expertise.
- Participate and staff the Planning and Coordination Committee (PCC) meetings.
- Fund travel of PCC members to in person meetings and technical consultations
- Convene an independent review panel of experts to provide an objective review of the submitted applications.
- Abide by the collaborative guidelines described in the Data Use Agreement.
- Providing CSTE staff to support the day to day activities of the IISP project at both CSTE and CDC.

CDC/Influenza Division Responsibilities

CDC/Influenza Division will have substantial programmatic involvement as described below:

- If IRB review is deemed necessary at the state/local level, CDC will assist in the development of a protocol that will be acceptable for local site IRB review and approval.
- CDC will provide technical assistance concerning laboratory methods for the detection of influenza if needed and may perform or suggest quality control testing of the laboratory methods used to diagnose influenza at each funded site.
- CDC will provide or facilitate receipt of technical assistance to laboratories for the detection of non-influenza respiratory viruses.
- CDC will provide the reporting mechanism and maintain a database for all project related data including ILI and patient visit tallies and the specimen related case report form.
- CDC will work with awarded applicants as needed to establish surveillance and determine appropriate methods to define the patient population.
- CDC will provide templates for data collection forms, which are found in the Appendices A and B of the original funding announcement. Forms include those that could be used for daily ILI and for reporting of influenza testing results CDC and the applicants selected for this project will together finalize the forms.
- CDC will ensure appropriate training for personnel from state health departments, including appropriate laboratory personnel before the start of the project.
- Participate on an independent review panel convened by CSTE to provide an objective review of the submitted applications.
- CDC will provide the reporting mechanism and maintain a database for all project related data including ILI and patient visit tallies and the specimen related case report form.
- Abide by the collaborative guidelines described in the Data Use Agreement.

Reporting Guidelines

Seller agrees to provide CSTE reports as requested and agrees to perform all activities described in the application submitted for this project. Progress reports will be required quarterly and should be submitted to nbryan@cste.org (Nicole Bryan) by **January 1, 2015, April 1, 2015, and June 30, 2015**.

A final report (guidelines TBD), final invoice, and all deliverables unless previously outlined will be prepared upon study completion. **All deliverables (invoice and final report) must be received by CSTE by June 30, 2015.**

Attachment II

INFLUENZA INCIDENCE SURVIELLANCE PROJECT

2014 - 2015 BUDGET PROPOSAL

SITE NAME: Los Angeles County

Epidemiologic/Coordination Personnel (include contractual) — **Epi Personnel Total: $ 53,177**

Name	Title	% Time	Pay rate	Salary Total	% Fringe	Fringe Total	TOTAL
TBD	*Epidemiology Analyst*	*50*	*$ 62,807*	*$ 31,403*	*52.693*	*$ 16,547*	*$ 47,951*
TBD	*Student Prof. Worker*	*20*	*$ 26,130*	*$ 5,226*	*0*	*$ -*	*$ 5,226*

Travel — **Travel Total: $ 133**

Description	Calculation for cost (ex: # sites x # miles x cost per mi)	Transportation total	Lodging	Lodging Total	Per Diem	TOTAL
Site visits	*5 sites*50 miles*$.53/mi*	*$ 133*				*$ 133*

Supplies, Equipment IT Services (include office space, if nec.) — **Supply Total: $ -**

Description	Cost	Frequency	TOTAL
N/A			

Incentives/Contractual Compensations — **Incentives Total: $ 10,000**

Description	Cost	Frequency	TOTAL
Gift cards: 5 sites$200/site/mo *12 mo.*	*$ 1,000*	*10*	*$ 10,000*

Courier Service — **Courier Total: $ 4,800**

Description	Cost	Frequency	TOTAL
Estimate $400/mo	*$ 400*	*12*	*$ 4,800*

Laboratory Personnel (include contractual) — **Lab Personnel Total: $ 28,427**

Name	Title	% Time	Pay rate	Salary Total	% Fringe	TOTAL
TBD	*PH Microbiologist*	*20*	*$ 74,634*	*$ 14,927*	*52.693*	*$ 22,792*
TBD	*Lab Assistant*	*10*	*$ 36,905*	*$ 3,691*	*52.693*	*$ 5,635*

Laboratory Supplies ***(a few possible costs are listed that we would like to have specified individually)*** — **Lab Supply Total: $ 189**

Description	Quantity	Cost per item	Frequency	TOTAL
Specimen collection kits	*1*	*$ 189*	*1*	*$ 189*
Swabs				
Transport media				
Specimen shipping to PHL				
Specimen storage costs				

Virologic Testing ***(a few possible costs are listed that we would like to have specified individually)***

Testing Total: $ 13,692

(Not required , but if data available, please itemize costs that are IRR supported, just don't add to the "Total" column)

Description	Vendor/Reagent	Quantity	Cost per quantity	# specimens	TOTAL
Test supplies (plastics, PEP, etc.)	*Fisher Scientific*	*10*	*$ 310*	*300*	*$ 3,100*
Extraction kits					*$ -*
Influenza primers/probes					*$ -*
Master mix	*Fisher Scientific*	*2*	*$ 385*	*300*	*$ 770*
Extraction kits for non-influenza testing (if diff)					*$ -*
Multiplex or reagents for non-influenza testing					*$ -*
Master mix for non-influenza testing					*$ -*
Luminex RVP kits		*2*	*$ 4,745*	*300*	*$ 9,490*
Luminex controls and calibrators		*2*	*$ 166*	*300*	*$ 332*
					$ -

Project Subtotal

Subtotal: $ 110,418

Indir **30.016**

Indirect Total: $ 16,583

Description of Charge Structure (rate formula)	Rate	Category/item incurring indirect cost	Amout rate applied to	When are the charges applied?	TOTAL
*Total salary * rate*	*30.016*	*Salary*	*$ 55,247*	*incurred salary*	*$ 16,583*

Project Budget Total $ 127,000